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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,654	NADEAU ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-30,74,76 and 78* is/are pending in the application.

4a) Of the above claim(s) *9 and 16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-14,20-30,74,76 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/29/2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on April 30, 2009 and the response to Notice of Non-Compliant Amendment filed on June 1, 2009 have been entered. The claims pending in this application are claims 1-14, 16-30, 74, 76, and 78 wherein claims 9 and 16-19 have been withdrawn due to the restriction requirement and the election of species mailed on September 28, 2006. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on June 1, 2009. Claims 1-8, 10-14, 20-30, 74, 76, and 78 will be examined.

Claim Objections

2. Claim 20 is objected to because of the following informality: "oligonucleotide wherein" in line 5 should be ""oligonucleotide,wherein".

3. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 22 has included all limitations recited in claim 23. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claim 76 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide" is added to the newly amended dependent claim 76. Although the specification describes to add a splint oligonucleotide wherein a first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide (e.g., see Figures 2A and 5A), since claim 76 is dependent on claim 74, claim 76 is read as further combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first

portion of the second oligonucleotide and wherein the first portion of the first oligonucleotide hybridizes to the first portion of the second oligonucleotide, paragraph [00098] in page 24, Figures 2A-2C, paragraph [000118] in page 37, and Figures 5A-5B of the specification suggested by applicant fail to define or provide any disclosure to support combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide **and wherein the first portion of the first oligonucleotide hybridizes to the first portion of the second oligonucleotide** as recited in claim 76.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Response to Arguments

In page 16, first paragraph of applicant's remarks filed on April 30, 2009, applicant argues that "[A]pplicants have amended claim 76 to recite the method of claim 74 further combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with

the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide. The invention is clearly described in the specification, *inter alia,* at paragraph [00098] on page 24, Figures 2A-2C, paragraph [000118] on page 37, and Figures 5A-5B. Applicants submit that amended claim 76 complies with the written description requirement, and request withdrawal of the rejection".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because paragraph [00098] in page 24, Figures 2A-2C, paragraph [000118] in page 37, and Figures 5A-5B of the specification suggested by applicant only support combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide **and wherein the first portion of the first oligonucleotide does not hybridize to the first portion of the second oligonucleotide** but fail to provide any disclosure to support combining in step (i) a splint oligonucleotide comprising a first portion and a second portion, wherein a hybrid is formed wherein the first portion of the splint oligonucleotide hybridizes with the first portion of the first oligonucleotide and a second portion of the splint oligonucleotide hybridizes with the first portion of the second oligonucleotide **and wherein the first portion of the first oligonucleotide hybridizes to the first portion of the second oligonucleotide** as recited in claim 76.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8, 10-14, 20-30, 74, 76, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is rejected as vague and indefinite in view of step (iii). Since step (iii) does not require that 5' portion of the first or second oligonucleotide in the hybrid is single stranded, if 5' portion of the first or second oligonucleotide in the hybrid is double stranded, it is unclear why the 3' terminus of the first or second oligonucleotide can be extended and an amplicon can be produced. Please clarify.

9. Claim 20 is rejected as vague and indefinite in view of the phrase "displacing in step (iv) the second hybridization blocker oligonucleotide". Does this phrase mean displacing in step (iii) the second hybridization blocker oligonucleotide since step (iii) contains displacing step and step (iv) is extending step? Please clarify.

10. Claim 22 is rejected as vague and indefinite. Since claim 1 requires to displace the hybridization blocker oligonucleotide before producing the amplicon (see steps (iii) to (v)) and does not require to produce the amplicon in the presence of the hybridization blocker oligonucleotide, it is unclear how the hybridization blocker oligonucleotide can reduce formation of the amplicon by hybridization of the first and second oligonucleotides prior to forming said complex by a factor of at least 100-fold. Please clarify.

11. Claim 28 is rejected as vague and indefinite. Since claim 1 requires that the first or second analyte-specific binding entity is a protein while claim 28 requires that the first or second analyte-specific binding entity is a protein complex which is a complex formed by a protein and

other compound, claims 1 and 28 do not correspond each other and the protein complex recited in claim 28 is much broader than the protein recited in claim 1. Please clarify.

Response to Arguments

In page 19, last paragraph bridging to page 20, first paragraph of applicant's remarks filed on April 30, 2009, applicant argues that "[A]pplicants submit that the claims are clear and separate inventions. As detailed in the specification at paragraphs [000142]-[000147], pages 49-51, an analyte-specific binding entity may be a protein bound to an epitope and oligonucleotide probe, or a protein complex of unlabeled antibodies bound to an epitope that are then bound to labeled antibodies bound to the oligonucleotide probe".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although paragraphs [000142]-[000147] and pages 49-51 of the specification describe that an analyte-specific binding entity may be a protein bound to an epitope and oligonucleotide probe, or a protein complex of unlabeled antibodies bound to an epitope that are then bound to labeled antibodies bound to the oligonucleotide probe, since claim 1 requires that the first or second analyte-specific binding entity is a protein while claim 28 requires that the first or second analyte-specific binding entity is a protein complex which is a complex formed by a protein and other compound, claims 1 and 28 do not correspond each other and the protein complex recited in claim 28 is much broader than the protein recited in claim 1. Applicant can overcome this rejection by inserting the limitations recited in claim 28 into claim 1.

12. Claim 74 is rejected as vague and indefinite in view of step (ii). Since step (ii) does not require that 5' portion of the first oligonucleotide in the hybrid is single stranded, if 5' portion of the first oligonucleotide in the hybrid is double stranded, it is unclear why the 3' terminus of the second oligonucleotide can be extended and an amplicon can be produced. Please clarify.

13. Claim 74 or 76 is rejected as vague and indefinite in view of step (ii). Since step (i) only contains a first oligonucleotide and a second oligonucleotide wherein the first portion of the first oligonucleotide is capable of hybridizing to the first portion of the second oligonucleotide, after combining the analyte, the first proximity member and the second proximity member, only one hybrid comprising the first portion of the first oligonucleotide and the first portion of the second oligonucleotide can be formed. Since "at least one hybrid" in step (ii) means one kind or more than one kind of hybrids, it is unclear why more than one kind of hybrids comprising the first portion of the first oligonucleotide and the first portion of the second oligonucleotide can be formed in view of step (a). Please clarify.

Conclusion

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
August 24, 2009